UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

AMY ARNOLD,

Plaintiff,

v.

Case No. 2:22-cv-1951
JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Elizabeth P. Deavers

COOPERSURGICAL, INC., et al.,

Defendants.

OPINION AND ORDER

This matter is before the Court on Defendants CooperSurgical, Inc. ("CooperSurgical"), The Cooper Companies, Inc. ("TCC"), Utah Medical Products, Inc. ("UTMD"), and Femcare Ltd.'s ("Femcare") (collectively, "Defendants") motions to dismiss Plaintiff Amy Arnold's First Amended Complaint. (ECF Nos. 43, 44, 45, 59.) Also before the Court is Femcare's Motion to Strike Plaintiff's Exhibits Offered in Opposition to Femcare's 12(b)(6) Motion to Dismiss. (ECF No. 66.)

For the reasons set forth below, the Court **GRANTS** TCC motion to dismiss for lack of personal jurisdiction (ECF Nos. 44); **DENIES without prejudice** Femcare's motion to dismiss for lack of personal jurisdiction (ECF No. 59); **GRANTS** Plaintiff's request for limited jurisdictional discovery as to Femcare (ECF No. 60); **GRANTS** Femcare and CooperSurgical's motions to dismiss on Counts I and II of the Amended Complaint and **DENIES** their motions as to Count III (ECF Nos. 43, 59); **GRANTS** UTMD's motion to dismiss on Counts I and II of the Amended Complaint and **DENIES** UTMD's motion as to Count III (ECF No. 45); and **DENIES as moot** Femcare's motion to strike (ECF No. 66).

I. BACKGROUND

This products liability suit arises from injuries Plaintiff sustained in connection with the use of Filshie Clips, a medical device used in tubal ligations. (Am. Compl. ¶ 17, ECF No. 40.) Plaintiff brings her action against Defendants as the companies and/or successors in interest to the companies that designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, and/or sold the Filshie Clip that was surgically used in Plaintiff.

A. The Filshie Clip and Federal Oversight

The Filshie Clip, created by Marcus Filshie in the late 1970s, is a component of the "Filshie Clip System" for laparoscopic tubal ligation, which involves applying a titanium clip with silicone rubber lining around each fallopian tube. (*Id.* ¶¶ 19, 39.) In short, the clip exerts continuous pressure on the fallopian tube, prompting necrosis and decreasing the tube's size, eventually leading to fibrosis. (*Id.* ¶ 20.) The Filshie Clip is designed to remain permanently attached to the fallopian tube at its placement location, thus providing a long-term form of birth control.

The Filshie Clip, like all medical devices sold in the United States, is regulated by the Food and Drug Administration ("FDA"), which draws its regulatory authority in this area from the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act ("FDCA"). 21 U.S.C. § 360c *et seq*. The MDA's regulatory framework sets forth three distinct classes of devices based on their potential risks. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316–17 (2008). Class III devices, the class to which the Filshie Clip belongs, are subject to the most extensive federal oversight. *Id.* at 317. Generally speaking, a device is placed into Class III "if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is 'purported or represented to be for a use in supporting or sustaining human life or for a

use which is of substantial importance in preventing impairment of human health,' or 'presents a potential unreasonable risk of illness or injury.'" *Id.* (quoting § 360c(a)(1)(C)(ii)).

Before a Class III device can enter the U.S. marketplace, it must undergo a rigorous "premarket approval" ("PMA") process. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). PMA requires a manufacturer to submit a multivolume application comprising of, *inter alia*, "full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a 'full statement' of the device's 'components, ingredients, and properties and of the principle or principles of operation'; 'a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device'; samples or device components required by the FDA; and a specimen of the proposed labeling." *Riegel*, 552 U.S. at 318 (quoting § 360e(c)(1)). If the FDA reviews the application in-house (rather than referring it to a panel of outside experts), it typically spends an average of 1,200 hours, and grants premarket approval "only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.* (quoting § 360e(d)). In deciding whether to grant premarket approval, the FDA must "weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C).

If the FDA's review process leads to a device's PMA, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing § 360e(d)(6)(A)(i)). Should a manufacturer wish to make such a modification, it must follow the FDA's process for supplemental premarket approval, an evaluation process that largely mirrors that of the initial application. *Id.* Following PMA, "the devices are subject to reporting

requirements," including the obligation "to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred." *Id.* (citing 21 C.F.R. § 803.50(a)).

In 1996, the FDA authorized the Filshie Clips' commercial distribution after granting the device premarket approval. (Am. Compl. ¶¶ 25-26, ECF No. 40.) Subsequently, the Filshie Clip System was marketed and sold throughout the United States, including in Ohio. (*Id.* ¶ 42.)

B. Plaintiff's Experience with the Filshie Clip System

In early 2003, Plaintiff underwent a tubal ligation procedure using Filshie Clips. (*Id.* ¶¶ 56-57.) Prior to this procedure, Plaintiff received a Disclosure and Consent detailing the related risks and hazards. (*Id.* ¶ 58.) The Disclosure and Consent did not, however, inform Plaintiff of the risk that the clip could migrate and the appurtenant damages entailing such a migration. (*Id.*)

In March of 2003, shortly after the tubal ligation, Plaintiff began experiencing pain and discomfort in her lower abdominal and pelvic region. (*Id.* ¶ 60.) This pain developed over the next 20 years, when, in January of 2022, Plaintiff's doctor identified a migrated Filshie Clip as the cause of her suffering. (*Id.* ¶ 62.) As of the time Plaintiff filed her complaint, she was in the process of scheduling a surgery to remove the clips. (*Id.* ¶ 64.)

C. Plaintiff's Complaint

As set forth in Plaintiff's Amended Complaint, Filshie Clips have subjected numerous unsuspecting women to significant injuries, stemming from the clips' propensity to migrate after implantation on the fallopian tubes. (*Id.* ¶ 44.) Whereas Defendants represented a .13% migration rate when seeking premarket approval, the actual rate, according to Plaintiff, is over 25%. (*Id.* ¶ 44, 49.) Despite this high rate, Defendants neither warned nor adequately informed Plaintiff or her healthcare providers how frequently these migrations occur or the attendant injuries that may

accompany such migration. (*Id.* ¶ 45.) This is so despite Defendants having received adverse reports concerning clip migration. (*Id.*) Rather than disclose the actual migration risk to the FDA, Defendants instead continued to market and promote the Filshie Clip System over other available procedures. (*Id.* ¶¶ 48, 51.) Defendants' actions allegedly breached their duty of reasonable care in the development and promotion of Filshie Clips and their duties as manufacturers and distributors of medical devices to continually monitor and test their product, thus subjecting Defendants to liability under the FDCA and Ohio product liability law. (*Id.* ¶¶ 52-54.)

Plaintiff asserts that, had Defendants complied with FDA regulations and Ohio product liability law, Plaintiff's injuries could have been avoided. (*Id.* ¶ 54.) Plaintiff therefore brings the following state law claims against all Defendants: (1) strict products liability for design defect, (2) strict products liability for manufacturing defect, and (3) strict products liability for failure to warn. (*Id.* ¶¶ 2, 77-111.) Defendants have each separately moved to dismiss Plaintiff's Amended Complaint in its entirety. (ECF Nos. 43, 44, 45, 59.) Plaintiff has filed her opposition (ECF Nos. 50, 51, 52, 60), to which Defendants have replied (ECF Nos. 53, 54, 55, 65). These motions are fully briefed and ripe for review.

II. LEGAL STANDARD

D. 12(b)(2)

Under Federal Rule of Civil Procedure 12(b)(2), a defendant may move to dismiss for lack of personal jurisdiction. "The party seeking to assert personal jurisdiction bears the burden of demonstrating that such jurisdiction exists." *Schneider v. Hardesty*, 669 F.3d 693, 697 (6th Cir. 2012) (quoting *Bird v. Parsons*, 289 F.3d 865, 871 (6th Cir. 2002)) When a court considers a motion to dismiss pursuant to Rule 12(b)(2) without an evidentiary hearing, as the Court does here, it must consider the pleadings and affidavits in the light most favorable to the plaintiff.

CompuServe, Inc. v. Patterson, 89 F.3d 1257, 1262 (6th Cir. 1996). In such an instance, the plaintiff "need only make a prima facie showing of jurisdiction." *Bird*, 289 F.3d at 871 (quoting *Neogen Corp. v. Neo Gen Screening, Inc.*, 282 F.3d 883, 887 (6th Cir. 2002)). The court may not weigh "the controverting assertions of the party seeking dismissal." *MAG IAS Holdings, Inc. v. Schmückle*, 854 F.3d 894, 899 (6th Cir. 2017) (quoting *Theunissen v. Matthews*, 935 F.2d 1454, 1459 (6th Cir. 1991).

E. 12(b)(6)

Federal Rule of Civil Procedure 12(b)(6) provides for dismissal of actions that fail to state a claim upon which relief can be granted. While Rule 8(a)(2) requires a pleading to contain a "short and plain statement of the claim showing that the pleader is entitled to relief," in order "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal,* 556 U.S. 662, 697 (2009) (quoting *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678 (clarifying plausibility standard articulated in *Twombly*). Further, "[a]lthough for purposes of a motion to dismiss [a court] must take all of the factual allegations in the complaint as true, [it is] not bound to accept as true a legal conclusion couched as a factual allegation." *Id.* at 678 (quoting *Twombly,* 550 U.S. at 555) (internal quotations omitted).

III. DISCUSSION

Defendants TCC, UTMD, and Femcare assert largely identical grounds for dismissal: (1) the Court lacks personal jurisdiction over these Defendants, (2) Plaintiff's Amended Complaint is an impermissible "shotgun pleading," and (3) Plaintiff's claims are preempted under the FDCA.

Defendant CooperSurgical does not seek dismissal on jurisdictional grounds; instead, CooperSurgical seeks dismissal solely under Rule 12(b)(6) on the same grounds as those set forth by its fellow Defendants.[1] The Court begins with the issue of personal jurisdiction.

A. Personal Jurisdiction

TCC, UTMD, and Femcare each argue that their contacts with Ohio are insufficient to allow the Court to properly exercise personal jurisdiction over them. (ECF No. 44 at 6-11; ECF No. 45 at 5-11; ECF No. 59 at 5-11.) The Court agrees only with respect to TCC.

"A federal court sitting in diversity may not exercise jurisdiction over a defendant unless courts of the forum state would be authorized to do so by state law—and any such exercise of jurisdiction must be compatible with the due process requirements of the United States Constitution." *Int'l Techs. Consultants, Inc. v. Euroglas S.A.*, 107 F.3d 386, 391 (6th Cir. 1997) (citation omitted). Thus, "[u]nder Ohio law, personal jurisdiction over non-resident defendants is available only if (1) the long-arm statute confers jurisdiction and (2) jurisdiction is proper under the Federal Due Process Clause."[2] *Conn v. Zakharov*, 667 F.3d 705, 712 (6th Cir. 2012) (citing *Kauffman Racing Equip., L.L.C. v. Roberts*, 930 N.E.2d 784, 790 (2010); *Goldstein v.*

[1] Defendants also contend that Plaintiff's Amended Complaint fails to state a claim for manufacturing defect. (*See* CooperSurgical's Mot. to Dismiss at 17-18, ECF No. 43; TCC's Mot. to Dismiss at 23-24, ECF No. 44; UTMD's Mot. to Dismiss at 23-24, ECF No. 45; Femcare's Mot. to Dismiss at 21, ECF No. 59.) Because the Court concludes that the FDCA preempts Plaintiff's manufacturing defect claim, *see infra* Section III.B.b, the Court declines to address whether the Amended Complaint states a valid claim for manufacturing defect.

[2] Presently, there is some uncertainty concerning the reach of Ohio's long-arm statute—namely, whether the statute is coterminous with the United States Constitution. *See QFS Transp., LLC v. Huguely*, No. 1:21-cv-00769, 2022 U.S. Dist. LEXIS 95329, at *10-12 (S.D. Ohio May 27, 2022) (discussing implications of the 2020 amendment to Ohio's long-arm statute and noting conflict among district courts as to whether the amended statute is now coterminous with federal constitutional limits); *AmaTech Grp. Ltd. v. Fed. Card Servs., LLC*, No. 1:21-cv-406, 2022 U.S. Dist. LEXIS 1655, at *10-13 (S.D. Ohio Jan. 5, 2022) (same). For the purposes of determining jurisdiction, the Court will assume—without deciding—that analyzing jurisdiction under Ohio's long-arm statute remains a separate inquiry. This assumption ultimately has no material effect on the adjudication of the jurisdictional issues Defendants' motions present—that is, because the Court cannot exercise personal jurisdiction over TCC consistent with the Due Process Clause, and because jurisdiction exists over UTMD under both Ohio's long-arm statute and the United States Constitution, the Court's resolution of the jurisdictional challenges remains the same regardless of whether the Court collapses Ohio's standard into the federal standard.

Christiansen, 638 N.E.2d 541, 543 (1994)). The court may begin its analysis under either standard, and if it finds jurisdiction improper under the first standard analyzed, it need not conduct a separate inquiry under the second standard. *See id.* at 711–12 ("Of course, if jurisdiction is not proper under the Due Process Clause it is unnecessary to analyze jurisdiction under the state long-arm statute, and vice-versa.").

Where there has been no evidentiary hearing on the merits of a 12(b)(2) motion, as is the case here, a plaintiff need only make a prima facie showing of personal jurisdiction. *Id.* at 711 (citation omitted). Plaintiff's burden is "relatively slight," and the court "must consider the pleadings and affidavits in the light most favorable to the plaintiff." *Am. Greetings Corp. v. Cohn*, 839 F.2d 1164, 1169 (6th Cir. 1988) (quoting *Welsh v. Gibbs*, 631 F.2d 436, 439 (6th Cir. 1980)). Though this burden is slight, the complaint still must "establish with reasonable particularity sufficient contacts between [the defendant] and the forum state to support jurisdiction." *Neogen Corp. v. Neo Gen Screening, Inc.*, 282 F.3d 883, 887 (6th Cir. 2002) (quoting *Provident Nat'l Bank v. California Fed. Savings Loan Ass'n*, 819 F.2d 434, 437 (3d Cir. 1987)). Accordingly, "[c]onclusory statements or bare allegations alone are insufficient to establish personal jurisdiction." *Morrison v. Taurus Int'l Co.*, No. 3:11-cv-322, 2012 U.S. Dist. LEXIS 162036, at *3 (S.D. Ohio Nov. 13, 2012).

a. UTMD

i. Federal Due Process Inquiry

The Court begins its analysis with the Federal Due Process inquiry, which, according to UTMD, requires the Court to decline exercising personal jurisdiction over them in this forum.

Under the Due Process Clause of the Fourteenth Amendment to the United States Constitution, for a court to constitutionally exercise personal jurisdiction over a defendant, the

defendant must "have sufficient 'minimum contact[s]' with the forum state so that finding personal jurisdiction does not 'offend traditional notions of fair play and substantial justice.'" *Conn*, 667 F.3d at 712 (quoting *Third Nat'l Bank v. WEDGE Group, Inc.*, 882 F.2d 1087, 1089 (6th Cir. 1989)). Personal jurisdiction under the Due Process Clause comes in two flavors: "(1) general personal jurisdiction, where the suit does not arise from defendant's contacts with the forum state; and (2) specific jurisdiction, where the suit does arise from the defendant's contacts with the forum state." *Id.* at 712–13. Plaintiff does not assert that the Court has general personal jurisdiction over UTMD; as such, the Court does not address its applicability to the case at bar.

For the court to exercise specific jurisdiction over a defendant, "[t]he plaintiff's claims 'must arise out of or relate to the defendant's contacts with the forum." *Ford Motor Co. v. Mont. Eighth Judicial Dist. Court*, 141 S. Ct. 1017, 1025 (2021) (quoting *Bristol-Myers Squibb Co. v. Superior Ct. of Cal., San Francisco Cty.*, 137 S. Ct. 1773, 1780 (2017)). As clarified by the Sixth Circuit, the Due Process Clause permits specific jurisdiction over UTMD only if its contacts with Ohio satisfy three conditions:

> First, the defendant must purposefully avail himself of the privilege of acting in the forum state or causing a consequence in the forum state. Second, the cause of action must arise from the defendant's activities there. Finally, the acts of the defendant or consequences caused by the defendant must have a substantial enough connection with the forum state to make the exercise of jurisdiction over the defendant reasonable.

Bird, 289 F.3d 865, 874 (6th Cir. 2002) (quoting *Southern Machine Co. v. Mohasco Indus., Inc.*, 401 F.2d 374, 381 (6th Cir. 1968)). The "critical question" that this inquiry addresses "is whether 'the defendant's conduct and connection with the forum State are such that he should reasonably anticipate being haled into court there.'" *Third Nat'l Bank*, 882 F.2d at 1089 (quoting *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1980)).

UTMD's contacts, as set forth in Plaintiff's Amended Complaint, satisfy all three conditions. Plaintiff's Amended Complaint asserts that the Court has specific jurisdiction over the Defendants because:

> [T]hey purposefully availed themselves of the privilege of conducting business in the state of Ohio and established minimum contacts sufficient to confer jurisdiction over these Defendants and the assumption of jurisdiction over Defendants will not offend traditional notions of fair play and substantial justice and is consistent with the constitutional requirements of due process.

(Am. Compl. ¶ 13, ECF No. 40.) The Amended Complaint continues:

> At all times relevant hereto and alleged herein, the Defendants conducted and continue to regularly conduct substantial business within the state of Ohio which included and continues to include, the research, safety, surveillance, manufacture, sale, distribution and/or marketing of Filshie Clips which are distributed through the stream of interstate and intrastate commerce in the state of Ohio, and within the Southern District of Ohio.

(*Id.* ¶ 15.) Finally, the Amended Complaint provides that UTMD "sell[s] their products and intend[s] that they be used by medical professionals treating patients in Ohio." (*Id.* ¶ 14.)

Considering the Amended Complaint in the light most favorable to Plaintiff, as the Court must, these allegations suggest that the Court's exercise of personal jurisdiction over UTMD is proper. The Amended Complaint states that UTMD "designed, manufactured, sold and distributed Filshie Clips and related equipment utilized in Plaintiff's tubal ligation," and that UTMD intended that its products "be used by medical professionals treating patients in Ohio." (Am. Compl. ¶¶ 14, 37, ECF No. 40.)

In response to the above allegations, the affidavit of UTMD's Chairman and CEO provides that UTMD "did not develop, manufacture, or market the Filshie Clips allegedly utilized in Plaintiff Amy Arnold's tubal ligation in early 2003." (Ex. A to UTMD Mot. to Dismiss, ECF No. 45-1.) The affidavit further states that, prior to February 2019, "UTMD did not sell or market the Filshie Clips in Ohio or elsewhere." (*Id.*) Additionally, the affidavit explains that "UTMD did not

design, research, conduct safety surveillance, develop, manufacture, test, label, package, distribute, market, or sell the Filshie Clips utilized in Plaintiff Arnold's tubal ligation in early 2003 as identified in Plaintiff's Complaint." (*Id.*) Given the contents of this affidavit, UTMD has successfully shifted the burden to Plaintiff to "set forth specific facts showing that the court has jurisdiction." *See Theunissen*, 935 F.2d at 1458.

Plaintiff has carried her burden. First, Plaintiff adequately shows that UTMD "purposefully availed" itself of the privilege of conducting business in Ohio—that is, Plaintiff has established that UTMD "should have reasonably foreseen" that its business activities "would have consequences in [Ohio]." *See Mohasco*, 401 F.2d at 382–83. "In the Sixth Circuit, the emphasis in the purposeful availment inquiry is whether the defendant has engaged in some overt actions connecting the defendant with the forum state." *Beydoun v. Wataniya Rests. Holding, Q.S.C.*, 768 F.3d 499, 506 (6th Cir. 2014) (quoting *Fortis Corporate Ins. v. Viken Ship Mgmt.*, 450 F.3d 214, 218 (6th Cir. 2006)). Here, Plaintiff directs the Court's attention to UTMD's marketing and promotion efforts as indicating that UTMD markets, sells, and distributes the Filshie Clip System in Ohio. (*See* Pl.'s Opp'n. to UTMD at 18, ECF No. 50 (noting that UTMD touts the Filshie Clip System as "Globally Recognized and Recommended" and "one of the most popular permanent sterilization methods in the United States, Canada and a significant number of countries worldwide").) Additionally, Plaintiff highlights UTMD's own admissions concerning its Ohio business activities and its exclusive U.S. distribution rights as further satisfying the purposeful availment prong:

> Utah Medical admits . . . that Utah Medical (1) has owned defendant Femcare, Ltd ("Femcare"), who manufactures the Filshie Clips, since 2011; (2) *currently* sells, markets, and distributes Filshie Clips in *Ohio*; and (3) has sold, marketed, and distributed Filshie Clips in the United States since *February 2019* when it purchased distribution rights [from] defendant CooperSurgical, Inc.

(*Id.* at 17-18.) Thus, as *the* nationwide distributor of "one of the most popular permanent sterilization methods in the United States," the Court finds that Plaintiff has sufficiently shown that UTMD "should have reasonably foreseen" that its business activities "would have consequences in [Ohio]." *See Mohasco*, 401 F.2d 374, 382–83 (6th Cir. 1968).

Plaintiff has also carried her burden to show that her claims arise from UTMD's activities in Ohio. This inquiry requires Plaintiff to "demonstrate a causal nexus between the defendant's contacts with the forum state and the plaintiff's alleged cause of action." *Beydoun*, 768 F.3d at 507. UTMD contends that there can be no causal nexus because it did not manufacture or sell the Filshie Clips utilized in Plaintiff's tubal ligation. (UTMD Mot. to Dismiss at 9-10, ECF No. 45.) Because UTMD had no involvement in the sale or marketing of the clips until 2019—more than 15 years after Plaintiff's tubal ligation—Plaintiff's claims do not arise from UTMD's activities in Ohio. (UTMD Reply at 1-2, ECF No. 55.) Thus, UTMD predicates its argument on the Court finding that the only conduct relevant to Plaintiff's claims is the implantation of the Filshie Clips in Plaintiff in 2003.

UTMD, however, takes too narrow of a view of the relevant conduct giving rise to Plaintiff's claims. Plaintiff's claims do not arise solely from her procedure in 2003, as UTMD argues; instead, Plaintiff's claims also arise from UTMD's ongoing contacts with Ohio occurring *after* Plaintiff's procedure. Plaintiff alleges that UTMD violated certain Ohio product liability statutes by marketing, promoting, selling, and distributing Filshie Clips while knowingly misrepresenting their potential harm and benefits. (*See* Am. Compl. ¶¶ 55, 109, ECF No. 40.) Further, UTMD's misrepresentations, which began in 2019, delayed Plaintiff's discovery of the source of her alleged injuries until 2022. As a consequence of this delay, Plaintiff allegedly sustained additional injuries that otherwise would have been avoided had UTMD complied with

Ohio's product liability statutes. (*See id.* ¶¶ 88, 98, 111 (noting Plaintiff "continues to sustain damages" due to the migrated clip); *see also* Pl.'s Opp'n to UTMD's Mot. to Dismiss at 20, ECF No. 50 ("Such statements regarding the safety of [UTMD's] products are one of the reasons why Ms. Arnold, her doctors, and [her] healthcare team were not able to discover the source of her pain sooner.").) Thus, the Court finds that Plaintiff has sufficiently demonstrated the existence of a "causal nexus" between UTMD's ongoing contacts in Ohio and her Ohio product liability claims. *See Beydoun*, 768 F.3d at 507.[3]

Third, the Court's exercise of jurisdiction over UTMD is reasonable. The reasonableness inquiry considers three factors, all of which weigh in Plaintiff's favor: "[1] the burden on the defendant, [2] the interests of the forum State, and [3] the plaintiff's interest in obtaining relief." *Beydoun*, 768 F.3d at 508 (quoting *Asahi Metal Indus. Co. v. Super. Court of Cal.*, 480 U.S. 102, 113 (1987)). Moreover, where the first two prongs of the Due Process inquiry are met, as is the case here, "'an inference of reasonableness arises' and 'only the unusual case will not meet this third criteria.'" *Air Prods. & Controls, Inc. v. Safetech Int'l, Inc.*, 503 F.3d 544, 554 (6th Cir. 2007) (quoting *Theunissen*, 935 F.2d at 1461). This is not an "unusual case." UTMD does not argue that it will face a burden defending itself in Ohio, and Plaintiff has a strong interest in obtaining relief in her home forum—the same forum in which UTMD currently conducts business. As for Ohio's interest, "it cannot be disputed that Ohio has an interest in resolving a suit brough by one of its residents against Defendants that purposefully availed themselves of acting and causing

[3] UTMD's reliance on *Harlow v. Children's Hosp.*, 432 F.3d 50 (1st Cir. 2005) is misplaced. In *Harlow*, the First Circuit found specific personal jurisdiction lacking because "[t]he bulk of Harlow's post-tort evidence of the Hospital's activity in Maine [was] simply not related at all to the alleged malpractice." *Harlow*, 432 F.3d at 61. Critical to the First Circuit's holding was the non-controversial proposition that "[f]or purposes of specific jurisdiction, contacts should be judged when the cause of action arose, regardless of a later lessening or withdrawal." *Id.* (quoting *Cambridge Literary Props. v. W. Goebel Porzellanfabrik G.m.b.H & Co. Kg.*, 295 F.3d 59, 66 (1st Cir. 2002)). Here, however, the Court finds that UTMD's alleged post-2019 conduct cannot be classified as "post-tort evidence" because Plaintiff predicates her claims, in part, on this exact alleged conduct. Put differently, whereas Harlow's proffered evidence was unrelated to her malpractice claim, UTMD's alleged conduct provides a basis for Plaintiff's claims.

consequences in Ohio." *Scotts Co. v. Aventis S.A.*, 145 Fed. Appx. 109, 115 (6th Cir. 2005) (quoting *Third Nat'l Bank*, 882 F.2d at 1092). Having satisfied each criterion of the Federal Due Process inquiry, the Court therefore finds the exercise of specific jurisdiction proper under the United States Constitution.

ii. Ohio's Long-Arm Statute

Satisfaction of the federal inquiry does not end the Court's analysis; the exercise of personal jurisdiction over UTMD must also be consistent with Ohio's long-arm statute. The Ohio long-arm statute allows for specific personal jurisdiction over any person who conducts business in the state of Ohio: "(A) A court may exercise personal jurisdiction over a person who acts directly or by an agent, as to a cause of action arising from the person's: (1) Transacting any business in this state[.]" Ohio Rev. Code § 2307.282(A)(1). This provision does not require a non-resident defendant to have a physical presence in Ohio. *Ohio Valley Bank Comp. v. Metabank*, No. 2:19-cv-191, 2019 U.S. Dist. LEXIS 160437, at *10 (S.D. Ohio Sept. 20, 2019). Thus, personal jurisdiction under the statute will lie if (1) the defendant has "transacted any business" in Ohio "directly or by an agent," and (2) the case deals with a "cause of action arising from" the business transacted in Ohio. Like Ohio courts, the Sixth Circuit gives the term "transacting business" a "broad interpretation." *Brunner v. Hampson*, 441 F.3d 457, 465 (6th Cir. 2006). In contrast to the broad interpretation applicable to the "transacting business" prong, the Sixth Circuit applies a more restrictive interpretation to the "arising from" requirement—that is, the long-arm statute "requires a 'proximate cause' relationship between a plaintiff's personal injury claim and the defendant's conduct in Ohio." *Id.* at 465–66.

Plaintiff satisfies both requirements under § 2307.282(A)(1). First, Plaintiff's undisputed allegations establish that UTMD has "transacted . . . business" in Ohio. *See* Ohio Rev. Code §

2307.282(A)(1). As set forth in Plaintiff's Amended Complaint, UTMD, CooperSurgical, and Femcare "sell their products and intend that they be used by medical professional treating patients in Ohio." (Am. Compl. ¶ 14, ECF No. 40.) The Amended Complaint also alleges that UTMD "conducted and continue[s] to regularly conduct substantial business within the state of Ohio," which includes the marketing and distribution of Filshie Clips, "which are distributed through the stream of interstate and intrastate commerce in the state of Ohio, and within the Southern District of Ohio." (*Id.* ¶ 15.)

For its part, UTMD does not dispute that, beginning in 2019, it conducted activities in Ohio. (*See* Ex. A to UTMD Mot. to Dismiss, ECF No. 45-1 (noting that "UTMD did not sell or market Filshie Clips in Ohio" before February 2019; *see also* UTMD Reply at 1, ECF No. 55 (arguing that UTMD's 2019-and-later "conduct in Ohio" did not give rise to Plaintiff's claims).) Instead, UTMD concentrates its arguments on § 2307.282(A)(1)'s second prong—that the "cause of action aris[e] from" UTMD's business transacted in Ohio. UTMD's arguments on this point largely mirror its arguments under the second *Mohasco* factor of the Federal Due Process inquiry—namely, that Plaintiff's cause of action is confined to Plaintiff's tubal ligation procedure occurring in early 2003.

But UTMD mischaracterizes the full extent of the conduct giving rise to Plaintiff's claims. As discussed under the federal inquiry, UTMD's ongoing contacts with Ohio, commencing in 2019, contributed to Plaintiff's delayed discovery of the migrated Filshie Clip, thus causing Plaintiff additional injuries that she otherwise would not have sustained had UTMD complied with Ohio's product liability laws. This is sufficient to satisfy the more restrictive "arising from" prong of Ohio's long-arm statute, which requires a proximate cause relationship between Plaintiff's claims and UTMD's conduct in Ohio.

Even assuming that the implantation of the Filshie Clip in 2003 proximately caused Plaintiff's injuries, as UTMD argues, UTMD's subsequent conduct allegedly injured Plaintiff further. Under Ohio law, such later-occurring conduct may constitute a proximate cause. *See McDougall v. Smith*, 191 Ohio App. 3d 101, 103–04 (Ohio Ct. App. 2010) (defining proximate cause as "a happening or event which as a natural or continuing sequence produces an injury without which the injury would not have occurred") (citing *Murphy v. Carrollton Mfg. Co.*, 575 N.E.2d 828 (Ohio 1991); *see also Murphy*, 575 N.E.2d at 830 ("It is a well-established principle of tort law that an injury may have more than one proximate cause."). Accordingly, the Court finds the "arising from" requirement satisfied. Therefore, having satisfied both requirements of § 2307.282(A)(1), in addition to having met the federal standard, the Court may properly exercise personal jurisdiction over UTMD. The Court therefore **DENIES** UTMD's motion to dismiss for lack of personal jurisdiction.

b. TCC

i. Federal Due Process Inquiry

The Court now turns to TCC—the parent corporation owning Cooper Medical, Inc., which owns Defendant CooperSurgical. (Ex. A to TCC Mot. to Dismiss, ECF No. 44-2.) In the interest of convenience, the Court will reprint the paragraphs of Plaintiff's Amended Complaint relevant to the Court's exercise of specific personal jurisdiction over TCC:

> 13. [T]hey purposefully availed themselves of the privilege of conducting business in the state of Ohio and established minimum contacts sufficient to confer jurisdiction over these Defendants and the assumption of jurisdiction over Defendants will not offend traditional notions of fair play and substantial justice and is consistent with the constitutional requirements of due process.
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> 15. At all times relevant hereto and alleged herein, the Defendants conducted and continue to regularly conduct substantial business within the state of Ohio which included and continues to include, the research, safety, surveillance, manufacture, sale, distribution and/or marketing of Filshie Clips which are distributed through the stream of interstate and intrastate commerce in the state of Ohio, and within the Southern District of Ohio.

(Am. Compl. ¶¶ 13, 15, ECF No. 40.)

The Court finds that Plaintiff's conclusory allegations concerning TCC fall far short of establishing "with reasonable particularity sufficient contacts" between TCC and the state of Ohio. *See Neogen Corp.*, 282 F.3d at 887. While Plaintiff broadly alleges that Defendants "purposefully availed themselves of the privilege of conducting business in the state of Ohio," Plaintiff alleges no specific facts suggesting that TCC ever had contacts with Ohio, let alone contacts sufficient to put TCC on notice that it should "reasonably anticipate being haled into court" in Ohio. *See Third Nat'l Bank*, 882 F.2d at 1089. Indeed, TCC's general counsel's affidavit states that: (1) "TCC did not design, research, conduct safety surveillance, develop, manufacture, test, label, or package the Filshie Clips allegedly utilized by Plaintiff," and (2) "TCC did not market, sell, or distribute the Filshie Clips in Ohio or elsewhere." (Ex. A to TCC Mot. to Dismiss, ECF No. 44-2.)

Plaintiff, who carries the burden to assert specific facts warranting the Court's exercise of personal jurisdiction, does not dispute the contents of TCC's affidavit. *See Theunissen v. Matthews*, 935 F.2d at 1458 ("[I]n the face of a properly supported motion for dismissal, the plaintiff may not stand on his pleadings but must, by affidavit or otherwise, set forth specific facts showing that the court has jurisdiction."); *see also* Pl.'s Opp'n. to TCC at 16-22, ECF No. 52. The "sine qua non" of personal jurisdiction is the purposeful availment factor, *see Theunissen*, 935 F.2d at 1460, and Plaintiff's failure to set forth *any* specific facts speaking to this factor leads the Court to conclude that TCC is not subject to the Court's jurisdiction. *See Maclin v. Reliable*

Reports of Tex., Inc., 314 F. Supp. 3d 845, 849 (N.D. Ohio Mar. 26, 2018) ("Failure to meet any one of the three prongs means that personal jurisdiction may not be invoked.")

ii. Alter Ego

Plaintiff alternatively argues that personal jurisdiction exists over TCC because it is the "alter ego" of CooperSurgical.[4] (Pl.'s Opp'n. to TCC's Mot. to Dismiss at 18-23, ECF No. 52.) The Court disagrees.

The Sixth Circuit recognizes that:

> it is compatible with due process for a court to exercise personal jurisdiction over an individual or a corporation that would not ordinarily be subject to personal jurisdiction in that court when the individual or corporation is an alter ego or successor of a corporation that would be subject to personal jurisdiction in that court.

Estate of Thomson ex rel. Estate of Rakestraw v. Toyota Motor Corp. Worldwide, 545 F.3d 357, 362 (6th Cir. 2008). In the parent-subsidiary context, as is the case here, the alter-ego doctrine holds that "a non-resident parent corporation is amenable to suit in the forum state if the parent company exerts so much control over the subsidiary that the two do not exist as separate entities but are one and the same for purposes of jurisdiction." *Id.* The alter-ego theory is akin to piercing the corporate veil of a parent corporation, and such veil piercing occurs only in "extraordinary cases." *Nottingham-Spirk Design Assocs. v. HALO Innovations, Inc.*, 603 F. Supp. 3d 561, 569 (N.D. Ohio May 19, 2022).

In applying the alter-ego theory of personal jurisdiction, the Court turns to Ohio law. *Id.* "In determining whether a subsidiary is an alter ego of the parent corporation, Ohio courts consider factors such as whether (1) corporate formalities are observed, (2) corporate records are kept, and (3) the corporation is financially independent." *Id.* Additional factors include "(1) sharing the same

[4] CooperSurgical does not contest personal jurisdiction.

employees and corporate officers; (2) engaging in the same business enterprise; (3) having the same address and phone lines; (4) using the same assets; (5) completing the same jobs; (6) not maintaining separate books, tax returns and financial statements; and (7) exerting control over the daily affairs of another corporation." *Id.* at 362–63.

At the outset, the Court notes that Plaintiff's Amended Complaint fails to include *any* allegations supporting her alter-ego theory. This, alone, warrants rejection of Plaintiff's alter-ego argument. *See Singh v. Daimler, AG*, 902 F. Supp. 2d 974, 982 (E.D. Mich. Oct. 10, 2012) ("Plaintiff's current complaint does not even *allege* personal jurisdiction via an alter ego theory or allege any facts [that] would provide a basis for the exercise of such jurisdiction. The Court could therefore, deny the motion on this basis alone.") (citing, *inter alia*, *Indah v. United States Sec. and Exchg. Comm'n*, 661 F.3d 914, 923 (6th Cir. 2011)).

But even when considering the allegations Plaintiff raised in her brief, she still falls short of setting forth a viable alter-ego theory. Plaintiff contends that TCC is "one and the same" for jurisdictional purposes, *see Estate of Thomson*, 545 F.3d at 362, citing (1) an overlap in officers who have held leadership positions in both TCC and CooperSurgical, at times holding leadership roles with each company at the same time; (2) TCC's officers and employees' involvement in CooperSurgical's activities, noting that CooperSurgical's president directly reports to TCC's president and CEO; and (3) multiple TCC press releases trumpeting certain TCC acquisitions beneficial to CooperSurgical. (Pl.'s Opp'n. to TCC's Mot. to Dismiss at 19-21, ECF No. 52.)

Plaintiff's allegations, taken as true, fail to present an "extraordinary" case warranting veil-piercing, and therefore the Court will not attribute CooperSurgical's jurisdictional contacts to TCC. Plaintiff makes much of the shared leadership between TCC and CooperSurgical, but "'it is

entirely appropriate for directors [and officers] of a parent corporation to serve as directors [and officers] of its subsidiary, and that fact alone may not serve to expose the parent corporation to liability for its subsidiary's acts.'" *Matthews v. Kerzner Int'l*, 2011 U.S. Dist. LEXIS 124727, at *11–13 (N.D. Ohio Oct. 27, 2011) (quoting *United States v. Bestfoods*, 524 U.S. 51, 69 (1998)).

Plaintiff's remaining allegations are insufficient to move the needle in favor of conferring jurisdiction over TCC. Indeed, it is what Plaintiff *does not* allege that demonstrates why her alter-ego argument falls short. Plaintiff does not provide any evidence that TCC has disregarded corporate formalities with regard to CooperSurgical and there is no evidence that CooperSurgical is financially dependent upon TCC or that the two companies comingle funds. *See Microsys*, 2006 U.S. Dist. LEXIS 53397, at *25 (N.D. Ohio Aug. 2, 2006) ("Sixth Circuit cases and Ohio law require demonstration of financial dependency between corporations and demonstration of nonobservance of corporate formalities. Microsys fails to demonstrate the state of financing between DDS and KAN, describe any commingling of funds between DDS and KAN, or detail KAN's nonobservance of corporate formalities.") (internal citations omitted). Plaintiff also fails to allege or put forth any evidence suggesting that TCC and CooperSurgical failed to maintain separate books, tax returns, and financial statements. Finally, while Plaintiff cites to a press release stating that CooperSurgical's president reports to TCC's president and CEO, Plaintiff has not presented other evidence of TCC "exerting control over the daily affairs of another corporation." *Estate of Thomson*, 545 F.3d at 362. On the balance of these factors, the Court concludes that Plaintiff has failed to meet her burden of establishing alter ego liability.

The Court also denies Plaintiff's request for limited jurisdictional discovery regarding TCC. (*See* Pl.'s Opp'n. to TCC's Mot. to Dismiss at 23, ECF No. 52.) Where a plaintiff fails to allege the alter-ego theory as a basis for jurisdiction in her complaint, that is generally enough to

find that the plaintiff has "not made a prima facie showing sufficient to obtain jurisdictional discovery." *In re Nat'l Prescription Opiate Litig.*, 2020 U.S. Dist. LEXIS 205381, *65 (N.D. Ohio Nov. 3, 2020); *see also Clockwork IP, LLC v. Clearview Plumbing & Heating Ltd.*, 127 F. Supp. 3d 1020, 1030 (E.D. Mo. 2015) ("Numerous cases hold that district courts have the discretion to deny jurisdictional discovery when, as here, the complaint fails to make a prima facie case of personal jurisdiction.") Here, it is undisputed that Plaintiff's Amended Complaint does not allege the alter-ego theory of personal jurisdiction. Given the absence of such an allegation, the Court finds that it would be an inappropriate exercise of discretion to allow jurisdictional discovery. Accordingly, the Court **DENIES** Plaintiff's request for limited jurisdictional discovery and **GRANTS** TCC's motion to dismiss for lack of personal jurisdiction.

c. Femcare

The Court now turns to the manufacturer of Filshie Clips: Femcare, which is based out of the United Kingdom. (Am. Compl. ¶¶ 7, 23, ECF No. 40.) Femcare argues that Plaintiff's Amended Complaint fails to allege sufficient facts establishing that this Court's exercise of specific jurisdiction comports with due process. (Femcare's Mot. to Dismiss at 8-12, ECF No. 59.) More precisely, Femcare contends that Plaintiff has failed to set forth sufficient facts upon which the Court can exercise personal jurisdiction under the Sixth Circuit's "stream of commerce 'plus'" theory of personal jurisdiction. (*Id.* at 8 (citing *Bridgeport Music, Inc. v. Still N the Water Publishing*, 327 F.3d 472, 479 (6th Cir. 2003)).) Under this theory, "for a defendant to purposely avail himself of the privilege of acting within a forum state, he must do more than merely place a product into the stream of commerce." *Parker v. Winwood*, 938 F.3d 833, 840 (6th Cir. 2019) (citing *Bridgeport Music*, 327 F.3d at 479). That is, in addition to placing a product in the stream of commerce, the defendant must show a specific intent to serve the forum's market. *Id.* at 841. In

arguing that Plaintiff failed to meet the "stream of commerce plus" standard, Femcare submitted an affidavit explicitly denying, *inter alia*, that Femcare has had any contact with Ohio, that it specifically directed the sale or distribution of Filshie Clips to Ohio, and that it ever sold Filshie Clips with the intent that they be used by medical professionals treating patients in Ohio. (Ex. 2 to Femcare's Mot. to Dismiss ¶¶ 8, 16-17, ECF No. 59.)

In response, Plaintiff argues that Femcare's relevant conduct satisfies the "stream of commerce plus" test because her claim arises out of injuries she sustained from a product that Femcare manufactured and knowingly had distributed to Ohio residents. (Pl.'s Opp'n to Femcare's Mot. to Dismiss at 12-20, ECF No. 60.) Critical to Plaintiff's argument is Femcare's exclusive distribution agreement with CooperSurgical, which grants in CooperSurgical the exclusive rights to sell Filshie Clips in the United States while retaining in Femcare a substantial amount of control over the sale, distribution, marketing, and safety of Filshie Clips. (*Id.*) Pursuant to the distribution agreement:

1. Femcare provided product samples, demonstration products, and promotional materials and publications to CooperSurgical for purposes of marketing the Filshie Clips;

2. Femcare was entitled to continue developing and making alterations to the Filshie Clips;

3. CooperSurgical was not permitted to make any representations "that have not been authorized in advance by" Femcare;

4. Femcare provided its own "qualified employee[s]" to CooperSurgical to assist with marketing, training, servicing the products, and for attending conferences with CooperSurgical;

5. CooperSurgical was obligated to consult with Femcare about "assessing the state of the market for the Products in the Territory [of the United States]"; and

6. CooperSurgical paid Femcare for Filshie Clips sales it made in the United States.

(Ex. C to Pl.'s Opp'n to Femcare's Mot. to Dismiss §§ 4.1, 4.2, 5.3, 5.5.2, 5.5.3, 5.5.4, 6.1, 8.1, 8.3, ECF No. 60-3.) In addition, Plaintiff asserts that Femcare maintains software systems that

allow Femcare to track every Filshie Clip that has ever been sold in the United States. (Pl.'s Opp'n to Femcare's Mot. to Dismiss at 15, ECF No. 60.)

Alternatively, Plaintiff requests that the Court grant limited discovery for the purposes of determining whether Femcare's contacts with Ohio are sufficient to give rise to personal jurisdiction. (Pl.'s Opp'n to Femcare at 20 n.40, ECF No. 60.) Such a request is consistent with Sixth Circuit precedent. *See Malone v. Stanley Black & Decker, Inc.*, 965 F.3d 499, 506 (6th Cir. 2020) (reversing district court's denial of jurisdictional discovery, recognizing the importance of jurisdictional discovery where plaintiffs were "two individual people" who cannot be expected to know the extent of the defendant manufacturer's contacts with the forum state).

Based on the facts presented, Plaintiff has shown that jurisdiction over Femcare *may* be consistent with the Federal Due Process Clause and Ohio's long-arm statute. But in the absence of additional evidence demonstrating that Femcare made the necessary contacts in Ohio—evidence that Plaintiff "could learn only through discovery," *see id.*—the Court finds that the prudent course of action is to permit jurisdictional discovery. *See Red Square, LLC v. HDAV Outdoor, LLC*, No. 2:14-cv-2064, 2015 U.S. Dist. LEXIS 117826, at *14 (S.D. Ohio Sept. 3, 2015) ("Although the plaintiff bears the burden of demonstrating facts that support personal jurisdiction, courts are to assist the plaintiff by allowing jurisdictional discovery unless the plaintiff's claim is 'clearly frivolous.'") (quotation omitted). Accordingly, the Court **GRANTS** Plaintiff's request for limited jurisdictional discovery and **DENIES without prejudice** Femcare's motion to dismiss for lack of personal jurisdiction.

B. Defendants' 12(b)(6) Arguments

Defendants TCC, UTMD, Femcare, and CooperSurgical also move to dismiss for failure to state a claim, arguing that Plaintiff's state law claims are preempted. Additionally, all

Defendants but Femcare argue that Plaintiff's Amended Complaint is an impermissible "shotgun pleading." The Court begins its analysis with the latter argument.[5]

a. Shotgun Pleading

Defendants TCC, UTMD, and CooperSurgical argue Plaintiff's Amended Complaint should be dismissed because it constitutes an impermissible "shotgun pleading." (CooperSurgical's Mot. to Dismiss at 5, ECF No. 43; TCC's Mot. to Dismiss at 11-12, ECF No. 44; UTMD's Mot. to Dismiss at 11, ECF No. 45.) The Court disagrees.

While the Sixth Circuit does not use the term often, a "shotgun pleading" is generally "a complaint containing multiple counts where each count adopts the allegations of all preceding counts, causing each successive count to carry all that came before and the last count to be a combination of the entire complaint." *Weiland v. Palm Beach Cty. Sheriff's Off*, 792 F.3d 1313, 1321 (11th Cir. 2015). When the Sixth Circuit has addressed "shotgun pleading," it did so in the context of a plaintiff's failure to separate his causes of action or claims for relief into separate counts. *Lee v. Ohio Educ. Ass'n*, 951 F.3d 386, 393 (6th Cir. 2020). Though "shotgun pleading" comes in a variety of types, *see Weiland*, 792 F.3d at 1323, n.3 (collecting cases), the characteristic unifying all types of shotgun pleadings is that they make it "virtually impossible for a defendant to know which allegations of fact are intended to support which claims for relief." *King v. G4S Secure Sols. (USA) Inc.*, No. 1:18 CV 448, 2019 U.S. Dist. LEXIS 28670, at *9 (N.D. Ohio 2019) (citing *Kaber v. Postmaster Gen. United States Postal Serv.*, No. 2:09-cv-01061, 2011 U.S. Dist. LEXIS 113663, at *5 (S.D. Ohio 2011)); *see also Darwish v. Ethicon, Inc.*, No. 1:20 CV 1606, 2020 U.S. Dist. LEXIS 228048, at *24 (N.D. Ohio 2020).

[5] Also before the Court is Femcare's motion to strike certain exhibits Plaintiff offered in opposition to Femcare's 12(b)(6) motion to dismiss. (ECF No. 66.) The challenged exhibits were immaterial to the Court's decision, and therefore the motion is **DENIED as moot**.

The Sixth Circuit analyzes a motion to dismiss in which a defendant raises "shotgun pleading" as grounds for dismissal by determining whether the complaint violates the Federal Rules of Civil Procedure. *Lee*, 951 F.3d at 393. Under Federal Rule of Civil Procedure 8, a plaintiff must "'connect specific facts or events with the various causes of action she asserted.'" *Id.* at 392–93 (quoting *Cincinnati Life Ins. Co. v. Beyrer*, 722 F.3d 939, 947 (7th Cir. 2013)). And Rule 8(a)(2) requires that defendants provide notice of the claims being brought against them and each claim's corresponding grounds. *Id.* Pleadings are sufficient under Rule 8 if a "brief reading" of them is enough for "the reader to determine which allegations of fact support the asserted claims for relief and it is possible to determine which causes of action are asserted against each defendant[.]" *King*, 2019 U.S. Dist. LEXIS 28670, at *9.

In *Lee*, the Sixth Circuit affirmed the district court's dismissal of plaintiff's complaint in part because plaintiff pleaded seven distinct causes of action in a single sentence, thus violating the Federal Rules of Civil Procedure. *Lee*, 951 F.3d at 393. But the complaint in *Lee* materially differs from the Amended Complaint here. Plaintiff's Amended Complaint does not allege all her causes of action in a single sentence; rather, Plaintiff asserts all her causes of action against all Defendants because they all allegedly developed, manufactured, distributed, marketed, or sold Filshie Clips during the relevant period.

The Amended Complaint here mimics that in *Rios v. Tower Hill Specialty Grp., LLC*, No. 1:20-CV-238, 2022 WL 980752, at *3 (S.D. Ohio Mar. 31, 2022). There, the Northern District held that plaintiff's amended complaint, which alleged all counts against each defendant, satisfied the Federal Rules of Civil Procedure. *Id.* at *6–8. In rejecting the defendants' argument that it was "impossible" to determine which allegations were against which defendant, the court noted that: (1) the plaintiff set forth unique factual matter for each count that went "beyond incorporating the

foregoing paragraphs," and (2) because the amended complaint explicitly alleged that the defendants were indistinguishable, plaintiff thus alleged that defendants were liable for all counts, and therefore it was not "impossible" to determine which allegations were against which defendants. *Id.*

Similar to the pleadings in *Rios*, Plaintiff's Amended Complaint does not make it "virtually impossible" for Defendants to know which facts support which claims. First, the Amended Complaint sets forth unique factual matter for each count that goes "beyond incorporating the foregoing paragraphs." (*See* Am. Compl. ¶¶ 78-88, 90-98, 100-111, ECF No. 40.) And second, the Amended Complaint alleges all claims against all Defendants due to Defendants' allegedly intertwined business relationships and the intertwined facts in the case. Thus, the Amended Complaint allows the reader to determine which causes of action are asserted against each defendant and the factual allegations supporting each claim for relief. Accordingly, the Court finds that Plaintiff's Amended Complaint does not constitute an impermissible "shotgun pleading."

b. Preemption under the Food, Drug, and Cosmetic Act

All Defendants have moved to dismiss Plaintiff's Amended Complaint as preempted under the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Medical Device Amendments of 1976, 21 U.S.C. § 301 *et seq.* ("MDA"). (CooperSurgical's Mot. to Dismiss at 5-17, ECF No. 43; TCC's Mot. to Dismiss at 12-21, ECF No. 44; UTMD's Mot. to Dismiss at 12-23, ECF No. 45; Femcare's Mot. to Dismiss at 13-20, ECF No. 59.)

The MDA preempts state law claims in two ways. First, the MDA includes a preemption provision expressly preempting certain state law requirements governing medical devices:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement–

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). Thus, "[s]tate requirements are pre-empted under the [MDA] only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law."[6] *Riegel*, 552 U.S. at 315 (quoting § 360k(a)(1)). The MDA does not, however, expressly preempt state law claims based upon "state duties [that] . . . 'parallel,' rather than add to, federal requirements." *Id.* In other words, the alleged conduct giving rise to a plaintiff's right to recover under state law must be conduct that is forbidden by the FDCA. As applied to the instant case, to determine whether Plaintiff's claims are expressly preempted, the Court must first identify what conduct by Defendants is alleged to give rise to a claim under Ohio law. If that conduct is not prohibited by the FDCA, the Plaintiff's claim, if successful, would have the effect of imposing on Defendants a requirement that is different from or in addition to the requirements imposed by the FDCA—and, for that reason, § 360k(a) would expressly preempt Plaintiff's claim.

But conduct that § 360k(a) does not expressly preempt may still be impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). In *Buckman*, the Supreme Court held that, because the federal government is the exclusive enforcing body of the FDCA, there is no private right of action under the FDCA. *Id.* at 349 n.4 ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions: '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.' 21 U.S.C.

[6] The parties do not dispute that the federal government has established requirements applicable to Filshie Clips as a Class III medical device. Nor should they. *See Riegel*, 552 U.S. at 332 ("Premarket approval . . . imposes 'requirements' under the MDA . . . .").

§ 337(a).”). Thus, a private litigant cannot sue a defendant for violating the FDCA. Nor can a private litigant bring a state law claim against a defendant when the state law claim is in essence a claim for violating the FDCA. *Id.* at 352–53. Instead, in order to avoid implied preemption, a claim must “rely[] on traditional state tort law which had predated the federal enactments in question[].” *Id.* at 353. Put differently, the alleged conduct giving rise to a plaintiff’s claim must be of the kind that would engender liability under state law notwithstanding the existence of the FDCA.

In sum, these two types of preemption create a “narrow gap” through which a plaintiff’s state law claim must fit to escape preemption. *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013). “The plaintiff must be suing for conduct that *violates* the FDCA (or else his [or her] claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).” *Id.* (quoting *In re: Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)). Accordingly, for a state-law claim to thread the preemption needle, the claim must be premised on conduct that (1) violates the FDCA and (2) gives rise to a recovery under state law even in the absence of the FDCA.

i. Count I - Design Defect

Plaintiff has raised a design defect claim against Defendants under Ohio Revised Code § 2307.75. Specifically, the Amended Complaint alleges:

> 78. The Filshie Clips are inherently dangerous and defective, unfit and unsafe for their intended use and reasonably foreseeable uses and does not meet or perform to the expectations of patients and their health care providers. These defects were not known to be unsafe by the ordinary consumer who consumes the product with the ordinary knowledge common to the community.
>
> 79. The Filshie Clips reached their intended consumer without substantial change in the condition in which they were in when they left Defendants’ possession.

> 80. The Filshie Clips were defective in design because they failed to perform as safely as persons who ordinarily use the products would have expected at the time of use.
>
> 81. The Filshie Clips used in Plaintiff were defective in design, because Filshie Clips' risk of harm exceed their claimed benefits. Namely, the Filshie Clips System as designed allows for migration from the implantation site which increases the risk of injury from the foreign body (the clips themselves) as they float freely.
>
> 82. The design was approved by the FDA without the benefit of the knowledge that Filshie Clips had a greater than .13% risk of migration. The incidence of migration is reported at 25%, a significant increase from the .13% currently reflected in the product information sheets. This information was available to the designer, manufacturer, and distributor at the time of the PMA. Further, the increased incidence of migration reported since 1996 was not reported to the FDA; a continued duty and requirement after obtaining the PMA. Such failure allowed for the defective design to remain the same.
>
> * * *
>
> 85. As a result of the foregoing defects, the Filshie Clips created risks to the health and safety of Plaintiff that were far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Filshie Clips.

(Am. Compl. ¶¶ 78-82, 85, ECF No. 40.)

Plaintiff's design defect claim is impliedly preempted under 21 U.S.C. § 337(a) and *Buckman*. Of particular note, the Amended Complaint fails to allege that the design of the Filshie Clips implanted in Plaintiff were anything other than the design the FDA approved via the PMA process. Thus, "'to prevail on this claim, Plaintiff[] would need to establish that the [medical device] should have been designed in a manner *different* than that approved by the FDA.'" *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1007 (S.D. Ohio 2016) (quoting *Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1040 (D.C. Haw. 2014)). But the Supreme Court's decision in *Riegel*—which held that § 360k(a) preempts "claims of strict liability . . . and negligence in the

design" of a device precludes such a claim. *Riegel*, 522 U.S. at 320. This is so because a claim alleging defective design would "necessarily 'establish design requirements different from, or in addition to, federal requirements for the [medical device].'" *Aaron*, 209 F. Supp. 3d at 1007 (quoting *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1222 (W.D. Okla. 2013)). If a state law required a medical device to have a design different from that approved by the FDA through the PMA process, it would present an impermissible "frontal 'attack on the risk/benefit analysis that led the FDA to approve' the device." *Id.* (quoting *In re: Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d at 1204). This would, therefore, be the exact type of claim that § 360k(a) preempts.

But Plaintiff's opposition asserts that her design defect claim is not preempted because she does not claim that the FDA's approved design and manufacture process of the Filshie Clips is defective; rather, Plaintiff asserts that her design defect claim survives preemption because it is predicated on Defendants' decision to continue the "manufacture and sale of Filshie Clips with the knowledge that they are dangerous and not reasonably safe and failing to comply with FDA manufacturing regulations." (Pl.'s Opp'n to UTMD's Mot. to Dismiss at 7, ECF No. 50; Pl.'s Opp'n to CooperSurgical's Mot. to Dismiss at 7, ECF No. 51; Pl.'s Opp'n to Femcare's Mot. to Dismiss at 5, ECF No. 60.) Plaintiff's Amended Complaint does not cite to any specific violations of the FDA, though a straightforward reading of the Amended Complaint makes clear that Plaintiff's design defect claim arises from Defendants' alleged failure to make required disclosures to the FDA.

For example, in Count 1 of the Amended Complaint, which sets forth the basis for Plaintiff's design defect claim, Plaintiff alleges that:

> 82. The design was approved by the FDA without the benefit of the knowledge that Filshie Clips had a greater than .13% risk of migration. The incidence

> of migration is reported at 25%, a significant increase from the .13% currently reflected in the product information sheets. **This information was available to the designer, manufacturer, and distributor at the time of the PMA. Further, the increased incidence of migration reported since 1996 was not reported to the FDA; a continued duty and requirement after obtaining the PMA. Such failure allowed for the defective design to remain the same**.

(Am. Compl. ¶ 82, ECF No. 40 (emphasis added).)

Plaintiff further alleges that Defendants' knowledge of the Filshie Clips' migration risk triggered duties under both Ohio product liability laws and the FDCA "to accurately report and update the FDA of the same." (*Id.* ¶ 53.) The Amended Complaint then succinctly sets forth the alleged facts that serve as the basis for her lawsuit: "If Defendants had timely disclosed the propensity and severity of risks associated with use of the Filshie Clips, Plaintiff's injuries could have been avoided. Instead, Defendants did nothing, and for that, Plaintiff here seeks redress both to compensate her for her losses and to strongly deter future, similar misconduct." (*Id.* ¶ 54; *see also id.* ¶ 48 ("The Plaintiff has suffered as a result of Defendants' failure to report adverse events involving the Filshie Clip. That failure violated requirements imposed by the Food and Drug Administration (FDA).").) Indeed, in Plaintiff's opposition briefs, Plaintiff speculates that had Defendants informed the FDA of the true risk of migration, "the FDA could have: (1) changed the labeling or marketing language Defendants are permitted to use to reflect accurate warnings or information about migration; (2) directly warned healthcare providers or the public about the risk of migration; (3) halted all sales of the Filshie Clips; or (4) recalled the defective Filshie Clips." (Pl.'s Opp'n to UTMD's Mot. to Dismiss at 10-11, ECF No. 50; Pl.'s Opp'n to CooperSurgical's Mot. to Dismiss at 10, ECF No. 51.) But Defendants allegedly did not inform the FDA of the Filshie Clips' migration risk, so the FDA did not require an alternative design or take other measures to prevent the injuries Plaintiff sustained.

Simply put, Plaintiff has failed to allege a factual basis for her design defect claim that is independent of Defendants' alleged failure to make certain disclosures to the FDA. Under Sixth Circuit precedent, this claim is impliedly preempted. In *Kemp*, the Sixth Circuit held that plaintiff's fraud-on-the-FDA claim arising from an allegedly defective pacemaker was preempted because "permitting a fraud claim premised on false representations to the FDA during the PMA process would conflict with well-established precedent that no implied private right of action exists under the FDCA." *Kemp v. Medtronic*, 231 F.3d 216, 236 (6th Cir. 2000). And in *Cupek*, a case involving allegedly defective pacemaker leads, the Sixth Circuit observed that it "is the Federal Government, rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (quoting *Buckman*, 531 U.S. at 349 n.4). Furthermore, the Sixth Circuit emphasized that a state law claim that is "a disguised fraud on the FDA" claim is preempted under *Buckman*. *Id.* That is precisely the type of claim before this Court: Plaintiff seeks to hold Defendants liable for their alleged misrepresentations and withholding of information to the FDA. As recognized in *Cupek*, it is for the federal government to prosecute suits for noncompliance with the MDA—not private plaintiffs.[7]

[7] A survey of courts across the United States reveals substantial agreement with the Sixth Circuit. *See, e.g., Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319 (11th Cir. 2017) ("Because this theory of liability is based on a duty to file a report with the FDA, it is very much like the 'fraud-on-the-FDA' claim that the Supreme Court held was impliedly preempted in *Buckman*"); *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010) (claim that manufacturer was negligent for "not timely fil[ing] adverse-event reports, as required by federal regulations" impliedly preempted as "simply an attempt by private parties to enforce the MDA"); *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1010 (S.D. Ohio 2016) ("The Sixth Circuit has squarely held that claims premised on an alleged "failure to submit reports to the FDA" are impliedly preempted by § 337(a), as interpreted by *Buckman*, because any such claim would be an impermissible attempt to enforce exclusively federal requirements with no counterpart in state law.") (citing *Marsh v. Genentech, Inc.*, 693 F.3d 546, 553 (6th Cir. 2012); *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 860 (W.D. Tenn. 2015) (claims based upon "failure to file adverse-event reports with the FDA . . . [are] impliedly preempted under *Buckman*"); *Byrnes v. Small*, 60 F. Supp. 3d 1289, 1297 (M.D. Fla. 2015) ("[T]o the extent that the claim is based on [an alleged] failure to report adverse events to the FDA, it is impliedly preempted"); *McClelland v. Medtronic, Inc.*, No. 6:11-CV-1444-Orl-36KRS, 2012 U.S. Dist. LEXIS 152197, at *18 (M.D. Fla. Sep. 27, 2012) ("[C]laims based upon FDCA disclosure requirements . . . are . . . impliedly preempted"); *Cales v. Medtronic, Inc.*, 2014 Ky. Cir. LEXIS 1, at *29 (failure-to-warn claim "predicated on . . . an alleged failure to submit adverse-event reports to the FDA would be impliedly preempted under *Buckman* and 21 U.S.C. § 337(a)") (quotation marks and citation omitted); *Froman v. CooperSurgical, Inc.*, No. 2:22-cv-00110-AKK, 2022 U.S. Dist. LEXIS 120725, *15 (N.D. Ala. July 8, 2022) ("[T]he 'FDCA's requirement for truthfully and completely reporting

Accordingly, the Court **GRANTS** Defendants' motions to dismiss as to Plaintiff's design defect claim (Count I).

ii. Count II - Manufacturing Defect

Plaintiff also raises a manufacturing defect claim against Defendants, arguing that Defendants are liable for any manufacturing defects in the Filshie Clips. Plaintiff's manufacturing defect claim, as set forth in the Amended Complaint, reads in pertinent part:

> 90. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, performed medical vigilance, distributed and sold the Filshie Clips that were used on Plaintiff.
>
> 91. The Filshie Clips used in Plaintiff contained a condition or conditions, which Defendants did not intend, at the time the Filshie Clips left Defendants' control and possession.
>
> 92. Plaintiff and Plaintiff's health care providers used the device in a manner consistent with and reasonably foreseeable to Defendants.
>
> 93. As a result of this condition or these conditions, the product failed to perform as safely as the ordinary consumer would expect, causing injury, when used in a reasonably foreseeable manner.
>
> 94. The Filshie Clips were defectively and/or improperly manufactured or constructed, rendering them defective and unreasonably dangerous and hazardous to Plaintiff.
>
> 95. Defendants had a duty to prevent the defective and/or improper manufacturing defects. This duty parallels the FDCA's requirement for truthfully and completely reporting incidents of adverse events, and if necessary, obtaining approval for changes in the design, manufacture, and warnings/marketing approved by the FDA.

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incidents of adverse events' is a duty that medical device companies owe to the FDA instead of to consumers. Consequently, all claims premised on the breach of this duty are squarely barred by the MDA's implied preemption provision.").

(Am. Compl. ¶¶ 90-95, ECF No. 40.)

Notably absent from the Amended Complaint is any allegation suggesting Defendants deviated from any specific FDA-prescribed manufacturing requirement. Nor does Plaintiff allege that the actual Filshie Clips implanted in her body varied from the FDA's requirements relating to the production of the clips. Therefore, "'to prevail on this claim, Plaintiff[] would need to establish that the [Filshie Clips] should have been designed in a manner *different* than that approved by the FDA.'" *Aaron*, 209 F. Supp. 3d at 1007 (S.D. Ohio 2016) (quoting *Beavers-Gabriel*, 15 F. Supp. 3d at 1040). As discussed in Section III.B.b.i, *supra*, the Supreme Court in *Riegel* foreclosed such a claim, holding that § 360k(a) preempts state law torts to the extent they would establish manufacturing requirements "different from, or in addition to" any federal requirements for Filshie Clips. *Riegel*, 552 U.S. at 330 (quoting § 360k(a)(1)). This is the same conclusion Judge Black reached in *Aaron*, where the Court found a design defect claim preempted under § 360k(a). 209 F. Supp. 3d at 1007. In *Aaron*, the Court held that "a state-law claim that would require a medical device to have a design *different from that approved by the FDA through the PMA process* is a frontal 'attack[] on the risk/benefit analysis that led the FDA to approve' the device." *Id.* (quoting *Bryant*, 623 F.3d at 1206) (emphasis added)). Yet this is precisely what Plaintiff's manufacturing defect claim seeks to do. Thus, allowing Plaintiff to proceed on this claim, given the absence of any allegation that Defendants failed to produce the Filshie Clips used in Plaintiff in accordance with FDA specifications per the PMA, "effectively results in a holding that an FDA-approved manufacturing process could nevertheless be legally insufficient and expose defendant to liability." *Warstler v. Medtronic, Inc.*, 238 F. Supp. 3d 978, 987 (N.D. Ohio 2017). As this Court concluded in *Aaron*, such a permissive decision would "encroach[] on federal regulatory authority

that 21 U.S.C. § 360(k) was specifically designed to prevent." 209 F. Supp. 3d at 1008. Accordingly, § 360k(a) expressly preempts plaintiff's manufacturing defect claim.

And to the extent Plaintiff predicates her manufacturing defect claim on Defendants' failure to "truthfully and completely report[] incidents of adverse events," Am. Compl. ¶ 95, ECF No. 40, such a claim is a "disguised fraud on the FDA" claim that is impliedly preempted under 21 U.S.C. § 337(a) and *Buckman*. (*See supra* Section III.B.b.i.) The Court therefore **GRANTS** Defendants' motions to dismiss on Plaintiff's manufacturing defect claim (Count II).

iii. Count III - Failure to Warn

Plaintiff's Amended Complaint alleges that Defendants are liable for Plaintiff's injuries due to Defendants' failure to warn that the Filshie Clips posed an unreasonable risk of migration from the implantation site. Specifically, the Amended Complaint states:

> 103. Defendants had a duty to warn of the risk of harm associated with the use of the device and to provide adequate warnings concerning the risk the device could migrate, even if used properly. This duty parallels the FDCA's requirement for truthfully and completely reporting incidents of adverse events, and if necessary, obtaining approval for changes in the design, manufacture, and warnings/marketing approved by the FDA.
>
> 104. The Defendants had a continuing duty to warn Plaintiff, Plaintiff's physician, and/or the medical community of the potential for migration of the Filshie Clips under the FDCA and parallel Ohio product liability laws.
>
> 105. Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers with regard to the inadequate research and testing of the Filshie Clips, and the complete lack of a safe, effective procedure for preventing migration. Rather, Defendants affirmatively advertised the safety of the Filshie Clip system vis a vis the alternative methods of bilateral tubal ligation, effectively downplaying even the de minimis risk of migration or expulsion reported to the FDA for approval of the device.

(Am. Compl. ¶¶ 103-05, ECF No. 40.)

Unlike Plaintiff's claims for design defect and manufacturing defect, the Court finds that Plaintiff's failure to warn claim evades preemption.

Plaintiff's Amended Complaint seeks to hold Defendants liable for their failure to warn Plaintiff, her physician, the medical community, and the FDA of the risk of harm associated with the use of Filshie Clips. Defendants contend that Plaintiff's claim is expressly preempted, relying heavily on the Sixth Circuit's decision in *Cupek*, 405 F.3d 421 (6th Cir. 2005). (CooperSurgical Reply at 6-8, ECF No. 53; UTMD Reply at 15-17, ECF No. 55; Femcare Reply at 12-14, ECF No. 65.) But *Cupek* is not decisive—at least at this stage of the proceedings. In *Cupek*, the Sixth Circuit held that "[a]ny claim, under state law, then, that Defendant failed to warn patients beyond warnings required by the FDA . . . would constitute state requirements 'different from' or 'in addition to' the requirements of the federal PMA application and supplement process" and therefore the state law claim would not parallel the FDCA violation. *Id.* at 424. According to Defendants, the allegations in Plaintiff's Amended Complaint—*i.e.*, that Defendants failed to adequately warn of the Filshie Clips' migration risk—would result in requiring Defendants to issue warnings *beyond* those required by the FDA.

The Court is not persuaded. Critically, Plaintiff carefully drafted her Amended Complaint to *avoid* alleging that Defendants failed to provide warnings "beyond" those required by the FDA—that is, Plaintiff's Amended Complaint strictly limits her FDCA failure-to-warn allegations to those that *parallel* Ohio's product liability laws. (*See* Am. Compl. ¶¶ 103-04, ECF No. 40.) This distinction matters. By cabining the extent of her claim, Plaintiff has ensured that, based on her pleadings, her failure to warn claim avoids express preemption under § 360(k)(a).

Plaintiff's Amended Complaint also skirts the trappings of implied preemption under § 337(a) and *Buckman*. The Amended Complaint does this by relying on Ohio Revised Code §

2307.76—a "traditional state tort law which had predated the federal enactments in question[]." *See Buckman*, 531 U.S. at 353.

This Court's decision does not contradict Sixth Circuit precedent, as Defendants contend. Indeed, the Sixth Circuit has suggested that a failure to warn claim mirroring Plaintiff's claim can avoid preemption. *See Kemp*, 231 F.3d 216 (6th Cir. 2000).[8] In *Kemp*, the Sixth Circuit indicated that a plaintiff could allege a viable cause of action under Ohio Revised Code § 2307.76 against a defendant manufacturer if the manufacturer acquired information subsequent to the FDA approval of a medical device that would lead a reasonable manufacturer to warn patients and the medical community. *Id.* at 236–37. This is exactly what Plaintiff's Amended Complaint alleges. (*See* Am. Compl. ¶¶ 103-05, ECF No. 40.) The Court therefore **DENIES** Defendants' motions as they relate to Plaintiff's failure to warn claim (Count III).[9]

The Court does wish to take a moment to remind the parties that it bases its decision on the pleadings, as it must. The "precise contours" of Plaintiff's theory of recovery are, admittedly, not well defined. *See Lohr*, 518 U.S. at 495. This lack of clarity by no means warrants dismissal of her claim, but it does hinder the Court's ability to "engage in a detailed comparison of the specific

[8] This Court has also found such claims sufficient to survive dismissal. *See Mories v. Boston Sci. Corp.*, 494 F. Supp. 3d 461, 472–73 (S.D. Ohio Oct. 14, 2020) (permitting failure to warn claim "alleging a breach of Defendant's duty under [Ohio Revised Code § 2307.76] to warn of potential defects, based on information Defendant obtained *after* the FDA's approval of the medical device.") (citing *Kemp*, 231 F.3d at 237); *Brooks v. Sanofi-Aventis U.S., LLC*, No. 2:14-cv-976, 2014 U.S. Dist. LEXIS 174842, at *5, 13 (S.D. Ohio Dec. 18, 2014) (denying defendant's motion to dismiss plaintiff's failure to warn claim as preempted); *Hawkins v. Medtronic, Inc.*, 909 F. Supp. 2d 901, 908–09 (S.D. Ohio Sept. 24, 2012) (denying defendant's motion to dismiss plaintiff's failure to warn claim where plaintiff alleged that "Defendant failed to provide adequate warnings and/or instructions, both at the time of marketing and afterwards").

[9] UTMD also suggests in its Reply brief that Ohio's statute of limitations for product liability actions bars Plaintiff's claims. (UTMD Reply at 3, ECF No. 55.) As an initial matter, the Court notes that a motion under Rule 12(b)(6) generally is an "inappropriate vehicle" for dismissing a claim based upon a statute of limitations. *Cataldo v. U.S. Steel Corp.*, 676 F.3d 542, 547 (6th Cir. 2012). But even if such a dismissal were warranted here, UTMD's brief discussion in its Reply is hardly sufficient to carry its burden on this issue. *See Lutz v. Chesapeake Appalachia, L.L.C.*, 717 F.3d 459, 464 (6th Cir. 2013) ("Because the statute of limitations is an affirmative defense, the burden is on the defendant to show that the statute of limitations has run[.]") (quoting *Campbell v. Grand Trunk W. R.R. Co.*, 238 F.3d 772, 775 (6th Cir. 2001)). Defendants may raise the statute of limitations issue at summary judgment, if appropriate.

state and federal requirements at issue." *Hawkins v. Medtronic, Inc.*, 909 F. Supp. 2d 901, 909 (S.D. Ohio Sept. 24, 2012); *see also id.* (holding that, to avoid preemption, the complaint need not define "the precise contours of [the plaintiff's] theory of recovery," if it alleges that the defendant has violated FDA regulations). For this reason, Plaintiff's claim is better suited for summary judgment after discovery. If discovery reveals that Plaintiff cannot sustain her claim while avoiding preemption, Defendants would, of course, be entitled to file a motion for summary judgment. Again, the Court does not rule on whether preemption will ultimately bar Plaintiff's claims, only that Plaintiff's Amended Complaint is sufficient to survive a motion to dismiss.

IV. CONCLUSION

For the reasons stated herein, the Court **ORDERS** as follows:

- TCC's Motion to Dismiss Plaintiff's First Amended Complaint is **GRANTED** for lack of personal jurisdiction. (ECF No. 44.) TCC is **DISMISSED without prejudice**;

- Femcare's Motion to Dismiss Plaintiff's First Amended Complaint is **DENIED without prejudice** regarding personal jurisdiction (ECF No. 59);

- Plaintiff's request for limited jurisdictional discovery as to Femcare is **GRANTED**. (ECF No. 60.) Plaintiff and Femcare shall have **sixty (60) days** from the date of this Opinion & Order to engage in limited jurisdictional discovery. Such discovery must be limited to jurisdictional issues raised in or relevant to Femcare's motion to dismiss for lack of personal jurisdiction. **Two weeks** after the close of the limited discovery period, Plaintiff may supplement its memorandum in opposition to Femcare's motion to dismiss for lack of personal jurisdiction. **Two weeks** after Plaintiff files a supplemental brief, Femcare may file a reply in support of its motion to dismiss for lack of personal jurisdiction;

- Femcare's Motion to Strike Plaintiff's Exhibits Offered in Opposition to Femcare's 12(b)(6) Motion to Dismiss is **DENIED as moot** (ECF No. 66);

- Femcare's Motion to Dismiss Plaintiff's First Amended Complaint under Rule 12(b)(6) is **GRANTED in part and DENIED in part**. (ECF No. 59.) The motion is **GRANTED** as to Counts I and II of Plaintiff's Amended Complaint on the basis that Plaintiff's claims are preempted. The motion is **DENIED** as to Count III of Plaintiff's Amended Complaint;

- CooperSurgical's Motion to Dismiss Plaintiff's First Amended Complaint is **GRANTED in part and DENIED in part**. (ECF No. 43.) The motion is **GRANTED** as to Counts I and II of Plaintiff's Amended Complaint on the basis that Plaintiff's claims are preempted. The motion is **DENIED** as to Count III of Plaintiff's Amended Complaint; and

- UTMD's Motion to Dismiss Plaintiff's First Amended Complaint is **GRANTED in part** and **DENIED in part**. (ECF No. 45.) The motion is **DENIED** to the extent UTMD asserts that the Court lacks personal jurisdiction over UTMD. The motion is **GRANTED** as to Counts I and II of Plaintiff's Amended Complaint on the basis that Plaintiff's claims are preempted. The motion is **DENIED** as to Count III of Plaintiff's Amended Complaint.

This case remains open.

IT IS SO ORDERED.

7/10/2023
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE